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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,718	07/14/2000	Bert L. Vallee	11187-00001	5959

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/616,718

Applicant(s)

VALLEE ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 3, 5-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Claims 3, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keung et al. *w/d*
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

The following is responsive to Applicant's amendment received Jul. 30, 2002.

Claim 4 is cancelled without prejudice.

No new claims are added. Claims 1-3, 5-6 are currently pending.

The previous rejection of claims 3, 5-6 under the judicially obviousness-type double patenting rejection over claims 1-10 of 5,886,028 is withdrawn in view of Applicant's amendment and the remarks contained therein.

The previous claims rejection under 35 USC 102(b), set forth in paragraphs 4-5 of the office action mailed March 13, 2002 is withdrawn in view of the new ground of rejection necessitated by Applicant's amendment.

Applicant's arguments traversing (1) the previous claims rejection under 35 U.S.C. 103(a) over Keung et al. and (2) the previous claims rejection under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of U.S. Patent No. 5,624,910 have been considered but are not found to be persuasive. *w/d*

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Said rejections are maintained essentially for the reasons given previously in the office action mailed March 13, 2002 with the following additional comment:

It is Applicant's position that the Keung et al. reference does not disclose the claimed compounds containing non-glucose sugar moieties. Similarly, the previous obviousness-type double patenting rejection over USPN '910 is overcome because USPN '910 does not claim compounds having non-glucose sugar moieties.

Said arguments have been considered but are not found to be persuasive.

Claim 3 as amended sets forth that "R" may be a "hexose" which encompasses the "glucose" moiety of daidzin. Therefore, Keung et al. disclose a compound, i.e. "daidzin" and USPN '910 claims a compound, i.e. "daidzin", which continues to be embraced by claim 3. Accordingly the rejections are maintained.

New Ground of Rejection

Applicant's amendment necessitated the following new ground(s) of rejection.

Claim Objections

3. Claim 3 is objected to because of the following informalities: in claim 3, at page 2, lines 1-2, "selected from the group consisting ofand/or.....and" is improper Markush terminology. The phrase should read --selected from the group consisting of....and....-. Please see MPEP 2173.05(h). Moreover, at line 1, after "aldo" and before "keto", the "and" should be deleted and replaced with --or--. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

4. Claims 3, 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 3 and 6, the term "biogenic" renders the claims vague and indefinite. The Examiner is unable to locate in Applicant's specification what is meant or embraced by the term "biogenic" aldehyde. The metes and bounds of the patent protection desired is unclear. w/d

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3, 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vallee et al., 5,204,369 or Vallee et al., 5,624,910.

Vallee et al., '369 disclose methods for treating alcohol dependence or abuse, the methods comprising administering effective amounts of daidzin. Please see the abstract; col. 14, lines 63-67; col. 16, lines 22-30; col. 21, lines 25-45. Additionally, Vallee et al. disclose at col. 14, lines 1-8 that improved inhibitory compounds may be obtained from synthetic derivatives of daidzin wherein the glucose is replaced with a different sugar moiety such as L and D aldo or keto-tetrose, pentoses, hexoses, heptoses, etc.

Vallee et al. do not specifically disclose that such synthetic derivatives may be useful in the treatment of alcohol dependence; however, the Examiner refers to Vallee et al., '910 which discloses methods for treating alcohol consumption or alcohol abuse, the methods comprising

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administering an effective amount of daidzin to reduce alcohol consumption. Please see the abstract; col. 10, lines 37-45; claims 1-6. Vallee et al., '910 additionally discloses synthetic derivatives of daidzin wherein the glucose may be replaced with a different sugar moiety such as L and D aldo or keto-tetrose, pentoses, hexoses, heptoses, etc. or that peptidic or polyether groups may be present. Vallee et al. teach that such examples will suggest to one of ordinary skill in the art routes of identification to daidzin derivatives having improved bioavailability, potency, selectivity, controlled release, solubility, absorbability and/or stability. Please see col. 13, lines 40-62.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the alcohol dependence treatment method of Vallee '369 to administer the daidzin derivatives disclosed by Vallee '369 and '910 because one of ordinary skill in the art would reasonably expect the derivatives to treat alcohol dependence. Such a modification would have been further motivated by Vallee '910's suggestion that from among the listed derivatives one of ordinary skill in the art would be able to determine the preferred derivatives useful in the treatment of alcohol dependence.

With respect to the increased concentrations of aldehyde such as those in claim 6, since Vallee '369 and '910 disclose administration of substantially similar active agents, i.e. daidzin and derivatives thereof, to a host, i.e. a human, using Applicant's claimed method steps then increased concentrations of an aldehyde such as those in claim 6 would have been obvious.

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Conclusion

Claims 3, 5-6 are rejected.

Claims 1-2 are free from the prior art.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

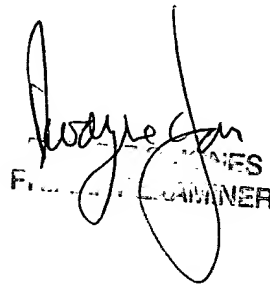
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Nov. 15, 2002


JUDY LE
F. LEANER